NO. 2 2 1 0 2

IN THE UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

HARRY SUGARMAN,

Appellant,

vs.

JACK B. FORBRAGD, et al.,

Appellees.

APPELLEES' BRIEF

APPEAL FROM
THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

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STATEMENT OF JURISDICTION

On March 31, 1967, appellant filed a Petition For Writ of Mandatory Injunction to compel employees of the Food and Drug Administration to admit certain fire-damaged coffee beans into this country unconditionally. [V. 1, pp. 1-5]. Appellant asserted that the District Court had jurisdiction under 28 U.S.C. 1361 and 5 U.S.C. 706 [formerly 1009(e)].

On May 15, 1967, the District Court filed an Order dismissing said Petition. [V. 1, p. 125]. In its Memorandum Opinion filed May 11, 1967, the District Court held

that it lacked jurisdiction over the subject matter. [V. 1, pp. 107-118]. The District Court further held that if it did have jurisdiction, it was convinced from its review of the case that the agency action complained of (refusing unconditional entry of the aforesaid damaged coffee beans) was not arbitrary or capricious, and that defendant would be entitled to a summary judgment. [V. 1, pp. 119-125].

On May 16, 1967, the District Court's Order of dismissal was entered. [V. 1, pp. 125-126]. On June 30, 1967, appellant filed a timely notice of appeal pursuant to 28 U.S.C. 2107. [V. 1, p. 127]. Appellant asserts that this Court's jurisdiction to review the judgment of the District Court rests upon 28 U.S.C. 1291.

We believe the holdings of the District Court are correct but we agree that this Court has jurisdiction under 28 U.S.C. 1291 to review such holdings.[1/]

1/ Appellant asserts that "this is an interlocutory appeal." [Appellant's Brief, p. 1]. We do not understand how this can be an interlocutory appeal when the District Court granted Respondents' Motion to Dismiss and in the alternative granted Respondents' Motion for Summary Judgment. [V. 1, p. 125]. See 28 U.S.C. 1292.

STATEMENT OF THE CASE

Appellant's "Statement of Proceedings Below" glosses over most of the significant facts and presents an unrealistic version of what happened. [Appellant's Brief, pp. 3-5].

The carefully considered Memorandum Opinion of the District Court, on the other hand, meticulously recites the underlying facts in this litigation. [V. 1, pp. 98-104; Sugarman v. Forbragd, 267 F. Supp. 817, 818-820]. We incorporate the District Court's "Statement of Facts" herein by reference.

All of the evidence in this case is in the form of documentary or physical exhibits. The Opinion of the District Court cites references to the exhibits upon which its "Statement of Facts" is based. Since the defendants' documentary exhibits have been repaginated on appeal, we have prepared the following tabulation for the convenience of the Court:

Defendants' Exhibits	Record on Appeal
1	V. 1, 47-56
1A	V. 1, 49; physical exhibit

Defendants' Exhibits	Record on Appeal
1B	V. 1, 50; physical exhibit
1C	V. 1, 51; physical exhibit
1D	V. 1, 52
1E	V. 1, 53
1F	V. 1, 54
1G	V. 1, 55
1H	V. 1, 56; physical exhibit
2	V. 1, 57
2A	V. 1, 58
2B	V. 1, 59-63
2C	V. 1, 64-65
2D	V. 1, 66-74
3	V. 1, 75
3A	V. 1, 76-85
4	V. 1, 86
5	V. 1, 87-88

Plaintiff's exhibits were not repaginated on appeal.

ARGUMENT

A. INTRODUCTORY STATEMENT

In its Memorandum Opinion, the District Court carefully considered every argument that was made by appellant in the proceeding below. We are wholly in accord with the reasoning and rulings of the District Court. We therefore incorporate the lower Court's Memorandum Opinion herein by reference. [V. 1, pp. 98, 107-124; 267 F. Supp. 817, 822-830].

Appellant now renews many arguments he made below and advances some arguments not made below. The rest of our brief will deal primarily with the latter arguments. We will also cite specific portions of the District Court's Memorandum Opinion where relevant.

B. AGENCY DETERMINATIONS REGARDING THE ADMISSIBILITY OF IMPORTS DO NOT REQUIRE A FORMAL HEARING OR AN "EXCLUSIVE RECORD FOR DECISION"

At the outset, we cite the relevant portion of the District Court's Memorandum Opinion. [V. 1, pp. 109-115; 267 F. Supp. 817, 823-826].

The statute in question, 21 U.S.C. 381(a), makes no provision for a formal hearing. An importer whose goods are detained when they are offered for entry into this country is given notice "and may appear before the Secretary of Health, Education, and Welfare and have the right to introduce testimony." As stated in The James J. Hill, 65 F. Supp. 265 (D. Md., 1946), at page 270:

> ". . . we are dealing with a subject matter of importation into the United States of articles where the power of Congress is absolute and the rights accorded the importer are only those given by the statute. The statute [section 381] accords a hearing only after notice to the importer with respect to the samples taken from the bulk of the commodity to determine whether it is properly importable. At the hearing upon notice the only right accorded to the importer is 'to introduce testimony.' Presumably this testimony should be relevant to whether the samples

are fairly illustrative of the bulk product, and if so whether the bulk product is properly importable."

[Emphasis added]

The informality of import proceedings provided by 21 U.S.C. 381(a) contrasts sharply with the formal administrative procedures specified in other provisions of the Federal Food, Drug, and Cosmetic Act. [V. 1, pp. 110-111; 267 F. Supp. at 824].

Appellant makes an elaborate web-spinning argument in an effort to show that Section 381(a) [2/] requires a formal hearing in which the agency action must be determined solely on the record of such hearing. [Appellant's Brief, pp. 30-36]. Appellant's purpose is to bring this proceeding within the scope of 5 U.S.C. 554(a) and 556(a) [3/] of the Administrative Procedure Act.

The short and decisive answer to this argument is that Section 381(a) speaks for itself. To read into it what appellant suggests calls for judicial legislation.

2/ Statutes are quoted in Appendix to Appellant's Brief.

3/ Same as footnote 2.

The Administrative Procedure Act does not superimpose the requirement of formal hearings in all administrative proceedings. It simply declares that where a statute requires an agency determination to be made "on the record" [5 U.S.C. 554(a)] then the procedural provisions of 5 U.S.C. 556(a) shall apply. Since Section 381(a) does not require agency determinations regarding imports to be made "on the record," appellant's argument is groundless. See Bridgeport Federal Savings and Loan Association v. Federal Home Loan Bank Board, 199 F. Supp. 410, 411-413 (E.D. Pa., 1961), aff'd 307 F. 2d 580, 581 (C.A. 3, 1962), cert. den. 371 U.S. 950, where it was held that the holding of an agency hearing did not require adherence to the procedural provisions of the APA, when neither the statute nor the regulations required the agency action "to be determined on the record after opportunity for an agency hearing." See also Appendix A of this brief for unreported opinion in another Food and Drug import case, Canadian Memorial Chiropractic College v. Shumate (W.D. N.Y., Civil 1966-189, July 26, 1967), where the Court stated on pages vi and vii:

"The statute gives the owner the right to introduce testimony. However, in the court's view, that right does not confer a right to a hearing as that term is ordinarily used, nor does the exercise of that right present a 'case of adjudication required by statute to be determined on the record after opportunity for an agency hearing' within the meaning of section 5 of the Administrative Procedure Act (5 U.S.C. §1004).

"In construing section 381, the broad power of Congress to regulate imports into the United States must be recognized. See Buttfield v. Stranahan, 192 U.S. 470 (1904); The Abby Dodge, 223 U.S. 166, 176-177 (1912). Unlike Wong Yong Sung v. McGrath, 339 U.S. 33 (1950), which is relied upon by plaintiff, the Constitution does not require a hearing to save this exercise of authority from invalidity."

To bolster his position, appellant presents a distorted view of Immigration and Deportation cases.

[Appellant's Brief, pp. 25-28]. A key point overlooked by appellant is stated in Leng May Ma v. Barber, 357 U.S. 185 (1958) at page 187:

> "It is important to note at the outset that our immigration laws have long made a distinction between those aliens who have come to our shores seeking admission, such as petitioner, and those who are within the United States after an entry, irrespective of its legality. In the latter instance, the Court has recognized additional rights and privileges not extended to those in the former category who are merely 'on the threshhold of initial entry.'"
>
> [Emphasis added]

An earlier decision emphasized the significance of this distinction. Shaughnessy v. U. S. ex rel. Mezei, 345 U.S. 206 (1953), where the Court said at page 212:

> "It is true that aliens who have once passed through our gates, even illegally, may be expelled only after proceedings conforming to traditional standards of fairness

encompassed in due process of law. . . . [citing cases including Wong Yang Sung v. McGrath, 339 U.S. 33]. But an alien on the threshhold of initial entry stands on a different footing: 'Whatever the procedure authorized by Congress is, it is due process as far as an alien entry is concerned.' . . . And because the action of the executive officer under such authority is final and conclusive, the Attorney General cannot be compelled to disclose the evidence underlying his determinations in an exclusion case; 'it is not within the province of any court, unless expressly authorized by law, to review the determination of the political branch of the Government.' . . . In a case such as this, courts cannot retry the determination of the Attorney General."

[Emphasis added]

Affirming a decision of this Court in a suspension of deportation proceeding, the Supreme Court said in Jay v. Boyd, 351 U.S. 345 (1956) at page 353:

"But there is nothing in the language of § 244 of the Act upon which to base a belief that the Attorney General is required to give a hearing with all the evidence spread upon an open record with respect to the considerations which may bear upon his grant or denial of an application for suspension to an alien eligible for that relief."

The analogy between the Immigration cases and the instant appeal is manifest. Here we have fire-damaged coffee beans which are at the threshhold of entry into the United States. The salvage operator who purchased them "as is" and "reconditioned" them has no constitutional right to a hearing "on the record" any more than has an alien seeking entry into the country. Buttfield v. Stranahan, 192 U.S. 470, 497 (1903). His only rights are those expressly conferred by 21 U.S.C. 381(a), namely, to receive "notice" and to "have the right to introduce testimony." He is given no right to require the agency to spell out the basis for its action "on the record," though in fact appellant was informed of the agency's views in advance of his opportunity "to introduce testimony." [Plaintiff's Exhibits A, C, F].

The analogy between food and drug cases and Immigration cases goes further. Once a food or drug is formally permitted entry into the country, it loses its import status under 21 U.S.C. 381(a). If it develops thereafter that the article is in violation of the adulteration, misbranding, or other provisions of the statute, the product may not be ordered to be destroyed or reexported by administrative action alone. Under such circumstances, there must be a judicial proceeding for condemnation under 21 U.S.C. 334(a) and (b), with a right to a jury trial. See 230 Boxes . . . of Fish v. U. S., 168 F. 2d 361, 364 (C.A. 6, 1948).

From the foregoing, it is manifest that appellant's argument relating to Wong Yang Sung v. McGrath, 339 U.S. 33 (1950)--[see Appellant's Brief, pp. 25-28]--gives misplaced emphasis to its significance since that case dealt with deportation rather than exclusion proceedings. See also Kwong Hai Chew v. Colding, 344 U.S. 590 (1953), especially footnotes 4 and 5 at page 596. The Immigration case which is in point here and which we have already discussed is Shaughnessy v. U. S. ex rel. Mezei, 345 U.S. 206, 212 (1953).

C. AGENCY DETERMINATIONS REGARDING THE ADMISSIBILITY OF IMPORTS ARE COMMITTED TO AGENCY DISCRETION BY LAW

At the outset, we cite the relevant portion of the District Court's Memorandum Opinion which considered and rejected most of the arguments offered on appeal by appellant. [V. 1, pp. 107-113; 267 F. Supp. 817, 822-825]. The District Court concluded that agency action in this case is "committed to agency discretion by law." For this reason, judicial review under the Administrative Procedure Act is precluded by the exception in 5 U.S.C. 701(a)(2).

Congress has plenary power with respect to imports. In 21 U.S.C. 381(a), it directed the Secretary to refuse admission of an import--

> "if it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions, or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article

is adulterated, misbranded, or in violation of section 355 of this title . . ."

Agency action is to be predicated upon the appearance of any of the three specified conditions, and such appearance in turn may derive from "the examination of such samples or otherwise." The agency is vested with the broadest possible discretion to keep out of the country foods, drugs, devices, and cosmetics which appear to be in violation of the Federal Food, Drug, and Cosmetic Act of this country, or the laws of the countries where they are produced or from which they are exported. The grounds for agency action may be obtained from foreign as well as domestic sources.

Congress deliberately chose a procedure that would commit discretion to the agency by law to act expeditiously with respect to the vast quantities of imports in this field. It conferred limited rights upon the importer to receive notice and "to introduce testimony" so that the agency would have an opportunity to evaluate the importer's views before reaching a final decision.

But Section 381(a) does not require the agency "to introduce testimony" nor does it state that the agency

determination must be based solely on a record of testimony introduced at a hearing. On the contrary, the language of the statute gives the agency unfettered authority to make its determination on information obtained from an examination of the sample or otherwise. Moreover, the statute does not permit judicial review of import determinations though, as shown earlier, judicial review is expressly authorized by the same Act with respect to many other agency actions. [V. 1, pp. 110-111; 267 F. Supp. at 824].

Here again, as in Section B of this argument, the Immigration cases are most closely analogous with respect to the reviewability of agency action under the Administrative Procedure Act. In Montgomery v. Ffrench, 299 F. 2d 730 (C.A. 8, 1962), the statute provided that an alien child could be admitted on a non-quota basis if the Attorney General was satisfied that the U. S. citizen, who had adopted the child by proxy and wished to bring the child here, had the ability to care for the child properly. The agency decision was to be made on petition of the citizen, and an "investigation of the facts" stated in the petition. The agency decision denying the petition

was held to be "agency action committed to agency discretion" and not reviewable under the Administrative Procedure Act. On page 734, the Court noted the distinction between exclusion and deportation cases, and stated:

> ". . . admission of an alien to this country is not a right but a privilege which is granted only upon such terms as the United States prescribes."

Also on page 734, the Court quoted from Brownell v. Tom We Shung, 352 U.S. 180, 182 (1956):

> ". . . in exclusion cases involving initial entry 'the decisions of executive or administrative officers, acting within powers expressly conferred by Congress, are due process of law.'"

The sole procedural distinction between Montgomery and the case at bar is that Montgomery presented his views in writing whereas Sugarman presented his views both orally and in writing. In both cases, the statutes delegated to the respective agencies complete discretion to investigate and evaluate the facts and make a final determination in

no way bound to a "record." Both cases involved "initial entry" into this country where the power of Congress is plenary and constitutional due process is not involved.

We believe it would take a strong showing of express Congressional intent to establish that agency action permitting conditional entry of fire-damaged coffee beans is reviewable under the Administrative Procedure Act, while agency action excluding an alien orphan and denying the petition of the child's adopted parents is not reviewable under that Act. See also Angelis v. Bouchard, 181 F. Supp. 551, 557 (D. N.J., 1960).

Using imprecise terminology and confusing various types of administrative procedures provided by the Federal Food, Drug, and Cosmetic Act, appellant mistakenly relies upon two recent Supreme Court decisions, Abbott Laboratories v. Gardner, 387 U.S. 136 (1967), and Toilet Goods Assn., Inc. v. Gardner, 387 U.S. 158 (1967). [Appellant's Brief, pp. 9-14, 20-21, 48-49].

The Abbott case arose out of legislation declaring a prescription drug to be misbranded unless its label

and labeling bear the "established" name of the drug printed prominently and in type at least half as large as the proprietary name or designation of the drug. [See pages 137-138]. By regulation, the Commissioner of Food and Drugs interpreted this statute to require the "established" name to accompany each appearance of the proprietary name or designation. The regulation simply gave the affected industry advance notice as to how the Commissioner intended to administer this law.

The regulation could only be enforced in a judicial proceeding--namely, through injunction, criminal, or seizure action, in which the United States would allege that a specific prescription drug was misbranded because the established name did not accompany each appearance of the proprietary name or designation. [21 U.S.C. 331(a), 332(a), 333(a), 334(a), 352(e)(1)(B)]. The key point is that ultimately the validity of this regulation would have to be tested in a judicial enforcement proceeding brought by the United States. [21 U.S.C. 337]. The question in Abbott was whether the case was ripe for judicial review in a pre-enforcement declaratory judgment proceeding brought by the manufacturers of more

than 90 per cent of the nation's prescription drugs. [See pages 138-139].

The Court noted that there is a pre-enforcement statutory review proceeding with respect to other types of food and drug regulations. [See pages 144-146]. The Court held that pre-enforcement judicial review of this regulation was not precluded by the statute, and that the case was in fact "ripe" for judicial resolution under the Declaratory Judgment Act and the Administrative Procedure Act. [See pages 148-153].

In the companion case of Toilet Goods Assn. v. Gardner, 387 U.S. 158 (1967), the validity of a different interpretive regulation was involved. There the Court held that pre-enforcement judicial review was inappropriate at that stage because the controversy was not yet ripe for adjudication.

Abbott and Toilet Goods Assn. concerned interpretive regulations affecting entire industries. The present appeal concerns a determination as to the admissibility of one lot of fire-damaged coffee beans which appellant

purchased for $600 "as is." [4/] The statute contemplates that interpretive regulations can be enforced only in a judicial proceeding, so that the issue in Abbott and Toilet Goods Assn. was not whether there should be a judicial proceeding to test the validity of the regulation, but when a judicial proceeding would be appropriate. On the other hand, the import statute contemplates no judicial proceeding whatsoever to review an agency determination made under that statute. [21 U.S.C. 381(a)].

In short, Abbott and Toilet Goods Assn. have no bearing on the applicability of the judicial review

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4/ Appellant seeks to raise the importance of this case to the Abbott level. On page 53 of his brief, he says:

> "The entire import industry dealing with foods, drugs, and cosmetics will be affected by this decision."

In Abbott, the petitioners included the manufacturers of more than 90% of the nation's supply of prescription drugs. [387 U.S. at 138-139]. In the present case, there is no hue and cry by the "import industry." Sugarman represents only himself and his joint venturers in this single salvage operation. [V. 1, pp. 87-88].

provisions of the Administrative Procedure Act to agency determinations under 21 U.S.C. 381(a). 5/

Concluding that the agency action in question was exempt from the Administrative Procedure Act and not subject to judicial review, the lower court appropriately held that it lacked jurisdiction and that the Petition should be dismissed.

D. THE DISTRICT COURT PROPERLY HELD THAT THE AGENCY ACTION WAS NEITHER ARBITRARY NOR CAPRICIOUS, AND THAT RESPONDENTS WERE ENTITLED TO SUMMARY JUDGMENT

After dismissing the Petition, the District Court nevertheless went on to examine appellant's assertion that the agency action was arbitrary and capricious. The Court declared that if its Order of dismissal should be found to be in error, it had reviewed the agency action

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5/ We do not attempt to refute every erroneous or misleading statement in appellant's brief. For example, on page 9, appellant declares that Abbott and Toilet Goods Assn. "held that the FDA must follow APA procedures in promulgating regulations." This was simply not the holding of those cases.

for reasonableness and had concluded that such action was not arbitrary or capricious. [V. 1, pp. 119-122; 267 F. Supp. 828-829]. It further held that respondents would then be entitled to a summary judgment. [V. 1, pp. 122-123; 267 F. Supp. 829-830].

As stated earlier, we adopt all of the reasoning of the lower Court in its Memorandum Opinion.

The lower Court noted that two earlier cases had considered agency action with respect to imports to be judicially reviewable to determine whether such action is arbitrary or capricious. Ambruster v. Mellon, 41 F. 2d 430 (Apps. D.C., 1930) and The James J. Hill, 65 F. Supp. 265 (D. Md., 1946).

Appellant mistakenly contends these cases stand for the proposition that there should be a trial de novo in the District Court regarding agency import actions. [Appellant's Brief, pp. 48-49]. In the Ambruster case, the plaintiff, a distributor of ergot of rye, sought to enjoin the agency from admitting competitive products into the country. Dismissal of the complaint was affirmed because the complaint (1) showed the agency had authority to act, and (2) failed to allege facts from which it

could be inferred that the agency action was arbitrary or capricious. There is no suggestion of a trial de novo in that case.

In The James J. Hill, the District Court took testimony on the admissibility of an import, but only for the purpose of determining whether the agency action was arbitrary or capricious, not to hold a trial de novo.

We believe the lower Court in the present case was correct when it stated:

> 267 F. Supp. 828:
>
> "The Court is satisfied that a broad inquiry into whether this agency action is 'arbitrary or capricious' is outside the jurisdiction of the Court. The only permissible inquiry is whether the statute is constitutional and whether the respondents acted within the scope of their statutory authority in reaching a decision . . . See Larson . . ." 6/

6/ This principle was recognized in The James J. Hill, 65 F. Supp. 265 (D. Md., 1946), where the Court noted at page 270:

> ". . . it is clear that in the present case the statute makes no provision for (Continued)

Nevertheless, the lower Court went on to review the voluminous record of documents and physical exhibits and concluded that the agency action was not arbitrary or capricious. We respectfully ask this Court to examine the lower Court's detailed exposition of the basis for its conclusion. [V. 1, pp. 119-122; 267 F. Supp. 828-829].

The Court further held that if it did have jurisdiction to consider both motions for summary judgment, the respondents were entitled to a summary judgment. [V. 1, pp. 122-123; 267 F. Supp. 829-830].

As the Court pointed out, "the only issue at this stage would be whether 'it appears from examination of

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6/ (Continued) judicial review and creates no personal federal rights as the basis for judicial review, so long as the Secretary acted within the scope of his authority under the Act."

[Emphasis added]

Thus the District Court in Hill properly stated the legal principle but improperly applied it by embarking on an inquiry as to whether the agency action was arbitrary or capricious. We believe the proper limits of a court inquiry are those defined in Larson v. Domestic and Foreign Commerce Corp., 337 U.S. 682, 689-690 (1949), and applied by the lower Court in the present case. [V. 1, pp. 115-117; 267 F. Supp. at 826-827].

* * * samples or otherwise that * * * such article is adulterated.' [21 U.S.C. 381(a)]." The evidence was uncontroverted that the charred coffee beans "appear" to be adulterated within the meaning of 21 U.S.C. 342(a)(3) in that they "appear" to be unfit for food.

A laboratory analysis was made of a sample of 12 pounds of these coffee beans. All of the beans were black on the surface. Six beans were cut in half, showing black color throughout the beans in all cases. The black beans left a black residue on the hands after examination. [V. 1, p. 53].

Another analysis consisted of (1) grinding the black coffee beans "as is," and brewing a beverage, and (2) roasting and grinding the black coffee beans and brewing a beverage. The first beverage had a slight smoky odor and flavor and a very slight odor and flavor of green coffee. The second beverage was nearly devoid of any coffee flavor and had a toasted flavor. Its color was very light, similar to light black tea beverage. [V. 1, p. 54].

The Court also had before it specimens of these charred coffee beans, unroasted and roasted [Defendants'

Exhibits 1A and 1H], as well as specimens of normal green coffee beans and normal roasted coffee beans. [Defendants' Exhibits 1B and 1C]. In addition, the Court had a comprehensive record of the manner in which these beans were damaged by fire, sea water, and smoke. [V. 1, pp. 98-101; 267 F. Supp. 818-819].

Petitioner did not refute these facts. He contended that an acceptable drink would result if these charred beans were "blended" with Brazilian coffee beans in the proportion of 10% to 90%, although the blending expert who testified for petitioner stated [Petitioner's Exhibit I-1, pp. 29, 30-37]:

> "In this case, this particular coffee with its changed profile, represented a, one might say, challenge."
>
> [Emphasis added]

After quoting this statement, the District Court commented [V. 1, pp. 121-122; 267 F. Supp. 829]:

> "This is a remarkable circumlocution and understatement, since the real issue was how to disguise these damaged beans through a blend and grind with normal

coffee beans so that the public might think the finished product is coffee."

Citing Federal Security Administrator v. Quaker Oats Co., 318 U.S. 218 (1943), for the principle that a major objective of the Food and Drug law is to preserve the integrity of the food supply and protect the consumer from economic adulteration, the Court continued:

> "Petitioner's proposal to blend the charred coffee beans with normal coffee beans is in reality a proposal to adulterate the good coffee beans, by substituting in part a cheapened and worthless commodity for genuine coffee beans. It is as though the proposal were to make a blend of used coffee grounds with freshly ground coffee. No doubt a skillful 'blending' of the charred coffee beans with genuine coffee beans, or of used coffee grounds with freshly ground coffee, would enable a coffee producer to palm off the finished product on an unsuspecting public as coffee.'"

Clearly, the charred coffee beans had the appearance of being adulterated since they were practically devoid of the characteristics of normal coffee. Thus the respondents were entitled to a summary judgment if the District Court had jurisdiction to reach that question.

E. THIS IS AN UNCONSENTED SUIT AGAINST THE UNITED STATES

Nominally this is a suit against two individuals. However, the suit is against those two individuals acting in a representative capacity as officers of the Government. Moreover, the suit seeks to compel the Government to take certain affirmative action--namely, to admit fire-damaged coffee beans into the country without the conditions heretofore imposed.

Unless the United States has expressly consented to be so sued, this is an unconsented suit against the sovereign, where the scope of judicial review is extremely limited. The leading case on this point is Larson v. Domestic and Foreign Commerce Corp., 337 U.S. 682 (1949),

which was carefully considered in the Memorandum Opinion of the District Court. [V. 1, pp. 115-118; 267 F. Supp. 826-828].

We maintain that this is an unconsented suit against the sovereign since, as we have already shown, (1) the import statute [21 U.S.C. 381(a)] does not provide for judicial review of agency determinations thereunder; (2) the Administrative Procedure Act [2 U.S.C. 706] does not provide for judicial review of such agency determinations because the challenged agency action is committed to agency discretion by law and is exempt from the APA by 5 U.S.C. 701(a)(2); and (3) other portions of the Administrative Procedure Act [5 U.S.C. 556(a) and 554(a)] are not applicable because neither the import statute [21 U.S.C. 381(a)] nor the Constitution requires such agency action "to be determined on the record after opportunity for an agency hearing."

Consequently, the only proper judicial review is that described in the Larson case, supra, as delineated in the Memorandum Opinion of the District Court, supra,--i.e., is the statute unconstitutional or were the officers' actions outside the statutory limitation of their powers?

As pointed out in footnote 4 of the Memorandum Opinion:

267 F. Supp. 827:

"For the Court to have jurisdiction, the action must be ultra vires the officer's authority. 'A claim of error in the exercise of that power is therefore not sufficient.' 337 U.S. at page 690, 69 S. Ct. at page 1461."

The lower Court properly concluded that it lacked jurisdiction to review the agency action since such action was well within the statutory authorization to act and there was no challenge of the statute's constitutionality. For these reasons, it dismissed the Petition.

CONCLUSION

Appellant's brief offers a welter of arguments which, on close examination, are without substance. As this Court observed in another food and drug case, Pasadena Research Laboratories, Inc. v. U. S., 169 F. 2d 375, 379 (C.A. 9, 1948), cert. den. 335 U.S. 853:

". . . we are here being asked to accept . . . refinements that we believe are as gossamer-like as the traditional 'shadow of a shade' of the ancient legal commentators."

We submit that the judgment of the District Court should be affirmed.

DATED: March 15, 1968.

Respectfully submitted,

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CERTIFICATIONS

I certify that, in connection with the preparation of this brief, I have examined Rules 18, 19, and 39 of the United States Court of Appeals for the Ninth Circuit, and that, in my opinion, the foregoing brief is in full compliance with those rules.

ROBERT N. ENSIGN
Assistant United States Attorney

This is to certify that I have this date sent three copies of this brief by certified mail to counsel for Appellant addressed as follows:

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DATED: March _____, 1968.

ROBERT N. ENSIGN
Assistant United States Attorney

APPENDIX A

UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF NEW YORK

CANADIAN MEMORIAL CHIROPRACTIC COLLEGE,

Plaintiff

-vs- CIVIL 1966-189

MERVIN H. SHUMATE, Food and Drug Officer, Food and Drug Administration, Buffalo District, Department of Health, Education and Welfare, et al.,

Defendants.

DECISION

Henderson, District Judge

UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF NEW YORK

CANADIAN MEMORIAL CHIROPRACTIC COLLEGE,

Plaintiff

-vs- CIVIL 1966-189

MERVIN H. SHUMATE, Food and Drug Officer, Food and Drug Administration, Buffalo District, Department of Health, Education and Welfare, et al.,

Defendants

Bass and Friend (Solomon H. Friend, Esq., of Counsel), New York, New York, Attorneys for Plaintiff.

John T. Curtin, Esq., United States Attorney (C. Donald O'Connor, Esq., of Counsel), for the Defendants.

The Food and Drug Administration has issued an order requiring that five synchro-therme skin temperature measurement devices, heretofore provisionally entered for importation into the United States, be exported or destroyed. The plaintiff, owner of the devices, has commenced this action claiming that the defendants acted beyond the scope of their authority, that the order is not

based upon any evidence, and that the order resulted from an unfair hearing not held in conformity with the Administrative Procedure Act (5 U.S.C. 1001 et seq.). The Government moves to dismiss the complaint or for summary judgment.

In his affidavit in opposition to the Government's motion, Andrew R. Petersen, the inventor of the device in question, describes the device as follows:

> "The Synchro-Therme device is not used to treat, cure or prevent any diseases or conditions in man. It is simply a temperature measurement device which is intended to measure the differential in temperature of two points on the surface of the skin of a human back in the vicinity of the spine. It measures the temperature in two places with two separate and distinct sensors, displaying these measure temperatures on adjacent scales for convenient comparison. These temperature readings are utilized by licensed practitioners as part of the examination of a patient, in the same sense that a stethoscope or an oral or rectal thermometer is used to examine a patient preparatory to a diagnosis which will enable the physician to prescribe an appropriate form of treatment. Based upon my experience in the use of the device and my discussions with numerous licensed practitioners who utilize the device, the directions accompanying the device are adequate, proper and complete to enable the practitioner to use the device for such purposes.

* * * *

"In this connection, I categorically and unequivocally state that the use of the Synchro-Therme by licensed practitioners to measure skin temperature gradients on the surface of the back is safe and that there is not even the remotest possibility that the device can have any untoward effect when used by licensed practitioners for such purposes.

"I wish to further inform this Court that this device has never been advertised to the lay public and has never been sold or leased to any member of the lay public. The fact of the matter is that the devices are provided only to duly licensed practitioners on a rental or lease basis and that plaintiff exerts full and complete control over the distribution thereof by reason of the periodic servicing and calibration requirements contained in each such lease."

For the purposes of these motions, the court, without deciding, will assume these statements are fact and will further assume that these facts were satisfactorily established in testimony before officials of the Food and Drug Administration. It is noted, however, that having acknowledged the device to be an aid to diagnosis, the plaintiff has assiduously avoided answering what significance its findings may have to a licensed chiropractor.

Section 381, Title 28 U.S.C. provides in pertinent part:

"(a) The Secretary of the Treasury shall deliver to the Secretary of Health, Education

and Welfare, upon his request, samples of . . . devices . . . which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health, Education and Welfare and have the right to introduce testimony. . . . if it appears from the examination of such samples or otherwise that . . . (3) such article is . . . mislabeled . . . then such article shall be refused admission. . . ."

A device is mislabeled "[u]nless its labeling bears . . . adequate directions for use . . ." 21 U.S.C. § 352. The term "adequate directions for use" is defined in pertinent part by 21 C.F.R. § 1.106 as follows:

> "(a) Adequate directions for use. Adequate directions for use means directions under which the layman can use a drug or device safely and for the purposes for which it is intended. Directions for use may be inadequate because (among other reasons) of omission, in whole or in part, or incorrect specification of:
>
> (1) Statements of all conditions, purposes, or uses for which such drug or device is intended, including conditions, purposes or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug or device is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the drug or device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner."
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> [Emphasis added.[

In the court's view, the statute and regulation in question are sufficiently broad to require a satisfactory showing that the device is neither a fraud nor, though a bona fide diagnostic aid, a device presenting findings requiring interpretations which are beyond the professional competence of licensed chiropractors. That the device, in and of itself, may be harmless does not end proper inquiry.[1]

The plaintiff argues that since the defendants have failed to show that the device is not completely safe when used by licensed chiropractors, the Government's motion must be denied. This argument misapprehends its burden under section 381.

The statute gives the owner the right to introduce testimony. However, in the court's view, that right does not confer a right to a hearing as that term is ordinarily used, nor does the exercise of that right present a "case of adjudication required by statute to be determined on the record after opportunity for an agency hearing" within the meaning of section 5 of the Administrative Procedure Act (5 U.S.C. § 1004).

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1. Cf. Drown v. United States, 198 F. 2d 999, 1006 (9th Cir. 1952).

In construing section 381, the broad power of Congress to regulate imports into the United States must be recognized. See Buttfield v. Stranahan, 192 U.S. 470 (1904); The Abby Dodge, 223 U.S. 166, 176-177 (1912). Unlike Wong Yong Sung v. McGrath, 339 U.S. 33 (1950), which is relied upon by plaintiff, the Constitution does not require a hearing to save this exercise of authority from invalidity.

The decision in this type of case often will turn solely upon the Administration's examination of the article or device. Unless it is apparent, as it was not in this case, that an article or device is properly labeled, facts demonstrating the propriety or impropriety of the labeling, or facts bringing the article within an exception contained in the regulations, although known to or obtainable by the owner or consignee, may well be unavailable to the Government. Administrative action, therefore, often may not be grounded upon the record of testimony offered by the owner or consignee but instead will be based upon its examination of the articles or devices involved.

Thus, recognizing the hardship under which the Government must operate, the statute quite logically does not hinge administrative action upon the outcome of an agency hearing but merely grants the owner or consignee a right to present testimony bearing on the admissibility of the goods. This is not to say, of course, that the Administration may arbitrarily refuse entry of articles or devices once all reasonable objection to their entry has been removed by evidence presented by the owner or consignee.

As previously indicated, the court is satisfied from the plaintiff's own view of its evidence that it failed to carry its burden in this case. Accordingly, the Government's motion for summary judgment is granted. This disposition, however, should not be taken as an endorsement of the Government's refusal to permit transcription of the proceedings involved. The net effect of this ruling is to presently permit the plaintiff to export its devices. If it wishes, it may again offer the devices for import and it may offer such additional and further testimony as it deems necessary to support their entry. A remand is not in order inasmuch as it

would give the plaintiff a further opportunity to meet deficiencies in its proof which is not envisioned by the statute.

Submit judgment.

/s/ John O. Henderson
JOHN O. HENDERSON
United States District Judge

DATED: July 26, 1967.